PATENT COOPERATION TREATY

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100926-1 WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 03/01910	International filing date *(day/month/year)* 08.12.2003	Priority date *(day/month/year)* 09.12.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/20		
Applicant ASTRAZENECA AB		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.06.2004	07.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kardas-Llorens, E Telephone No. +49 89 2399-8652

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/SE 03/01910

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-13 as originally filed

Claims, Numbers

1-29 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 20-27

   because:

   ☒ the said international application, or the said claims Nos. 20-27 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-28(partially) and 29 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-5, 7-13, 15-17, 19-29
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-29
Industrial applicability (IA)	Yes:	Claims	1-19, 28, 29
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The subject-matter of claims 20-27 is directed to a therapeutical method of treatment (Art. 34(4)(a)(I) and Rule 67.1 (iv) PCT).

For the assessment of the present claims 20-27 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item IV

Lack of unity of invention

The International Search Authority has considered that there are three inventions covered by the claims indicated as follows:

I: Claims: 1-28 (partially) and 29

II: Claims: 1-4, 7-14, 16-18 and 20-28

III: Claims 2-4, 9-14, 17-18 and 20-28

It was considered that the three inventions are not linked such that they form a single general inventive concept, as required by Rules 13.1, 13.2 and 13.3 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-B-6 228 857

D2: US-A-6 159 971

D3: EP-A-1 327 440

D4: PATENT ABSTRACTS OF JAPAN
vol. 1998, no. 10 31 August 1998
& JP 10 114 655 A (KYOWA HAKKO KOGYO CO LTD) 06 May 1998

Novelty:
Documents D1 and D2, each taken alone, are novelty destroying for the subject-matter of claims 1-5, 7-13, 15-17 and 19-29.
See in particular claims 1-19, column 3, l. 56-column 4, l. 29, column 4, l. 42-62, column 5 and 6 in D1. claims 1, 7, 17, column 4, l.24-column 5, l. 18, column 5, l. 36-61 in D2.
Attention is drawn to the fact that when determining novelty, the terms "Disintegrant" and "Binder" are interchangeable, since both terms can mean the same compound, see e.g. the compounds in present claims 5 and 9 and pages 5-6.
Furthermore, documents D3 and D4, each taken alone, are novelty destroying for the subject-matter of claim 29.
See in particular claims 1-12 and p. 5, l. 15 in D3 and the abstract in D4.
Also, the documents cited on present p. 2 are novelty destroying for the subject-matter of claim 29.

Inventive Step :
According to present p. 1 and 2 the problem to be solved is to prepare a dosage form which disintegrants in small granules upon contact with water, thereby making the active compound readily available after administration without any agglomerates being formed of the active compound. This has been presently achieved by adding disintegrants to the active compounds in the dosage form (see e.g. l. 25-27 on present p. 11).
However, it is considered that this problem has already been solved in a similar manner by using disintegrants in the known cited prior art. See e.g. the disclosures in D1 or D2. Also, the prior art cited on present page 2 as well as documents D3 and D4 teach the use of disintegrants for the preparation of dosage forms.
Thus, the subject-matter of claims 1-29 does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

Further comments:
-The features: " soluble filler" in claim 1, "low substituted hydropropyl cellulose" in claim 5, "a number of " in claim 7, " tmax" in claim 28 are not clear.
-The last two paragraphs of claim 5, which are disclosed on p. 15, seem to be erroneously attached to claim 5.